Six-Year Review Notice of Intent

Preliminary Revise/Not Revise Decisions for Existing Drinking Water Standards

Science Advisory Board Briefing

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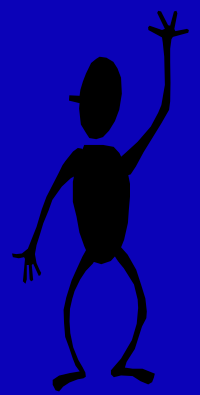
Targeting and Analysis Branch

Outline

- **Provide background on the Six-Year Review**
  - Statutory provision, internal and external involvement
  - Objectives of the Six-Year Review
  - Six-Year protocol and key elements considered
  - Meaning of the “revise/not revise” decision
- **Discuss preliminary “revise/not revise” decisions**
  - 68 preliminary “not revise” decisions (discussed by category)
  - One “revise” - Total Coliform Rule
- **Provide schedule and next steps**



What is the standard setting agenda required by the SDWA?

(SDWA Section 1412)

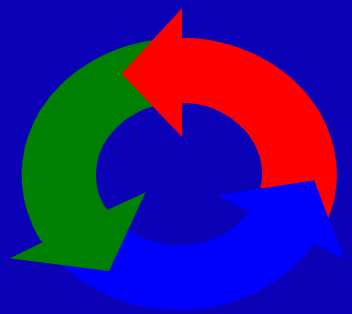
Initial Standard-Setting

(1) First mandated by Congress:

- Existing National Primary Drinking Water Regulations (NPDWRs) - based on requirements from 1986 SDWA Amendments.
- Current Setting of NPDWRs - based on 1996 SDWA- Promulgate standards for specific contaminants (e.g. radon, arsenic).

(2) EPA then mandated to determine what to regulate:

- Future NPDWRs - Based on 1996 SDWA - contaminant selection via Contaminant Candidate List (CCL).



Review of Existing NPDWRs

(3) Re-evaluate existing NPDWRs (1996 SDWA):

- Review and revise, as appropriate, existing NPDWRs every six years.
- Review of pre-SDWA 1996 NPDWRs needs to be completed in 2002.
- Review of post-SDWA 1996 NPDWRs will be included in future review rounds.

Background and Involvement

- **1996 SDWA Amendments - statutory requirement**

Section 1412(b)(9): *"the Administrator shall, not less often than every 6 years, review and revise, as appropriate, each primary drinking water regulation … any revision shall maintain, or provide for greater, protection of the health of persons."*

- **Involvement in the Six-Year Review Process**
  - Internal: OST, OGC, OPPTS, ORD, OPEI, OECA, OSWER, & Regions (1, 5, 7, 9 and 10)
  - External: Stakeholders, NDWAC, AWWA, ASDWA
  - SAB consultation tentatively planned for June time frame

Objectives of the Six-Year Review

- Develop a systematic protocol to review NPDWRs and to determine if there is a basis for considering revision. (Developed using NDWAC recommendations, includes several key elements)
- Review 69 NPDWRs* promulgated prior to 1996 (review complete)
- Publish Notice of Intent (NOI) describing protocol and preliminary revise/not revise decisions (Published on April 17, 2002)
- Publish final revise/not revise decisions ~ Fall 2002 timeframe

* Current review addresses NPDWRs promulgated before the 1996 SDWA Amendments (pre-1997 NPDWRs). These NPDWRs include 68 chemicals and the Total Coliform Rule. Remaining pre-1997 regulations reviewed in recent or ongoing rulemaking. EPA will review NPDWRs promulgated after 1997 at a later date.

Protocol - Key Elements Considered

- **Health Effects** - ID potential changes that may affect the MCLG
  - Review completed IRIS, OPP, ATSDR, and NAS assessments.
  - Where necessary - perform literature searches for developmental & reproductive end points and in some cases other toxicological end points.
- **Analytical Methods** - ID potential changes/limits in feasibility
  - Where MCL originally limited by practical quantitation level (PQL) or if potential for MCLG/MCL to decrease.
  - Evaluate more recent Water Supply data and/or compare method capabilities for “then” versus “now.”
- **Treatment Technology -** Evaluate feasibility if potential changes in MCLG/MCL. Also, if indication that best available technology (BAT) or treatment technique (TT) requirements need review.

Protocol - Key Elements Considered
(continued)

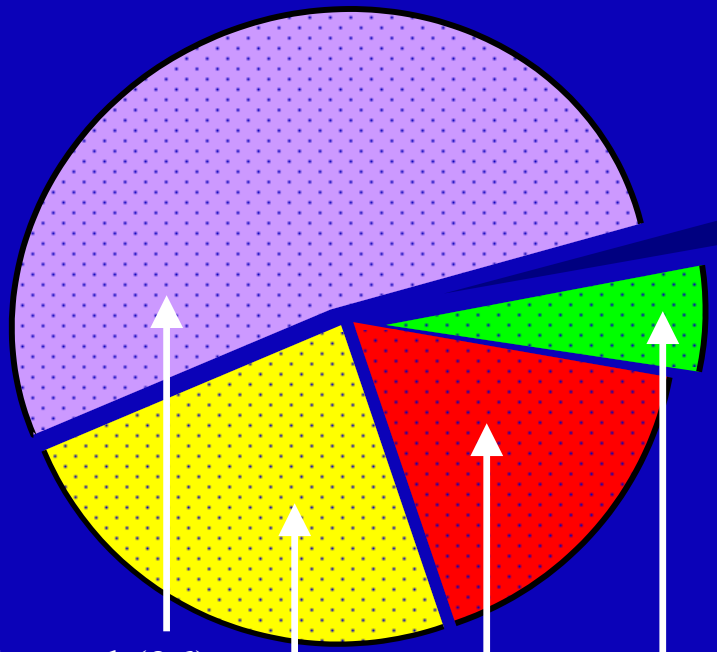
- **Other Regulatory Revisions**
  - Identify non-MCLG/MCL or non-TT types of changes that have not or are not being addressed through alternative mechanisms.
- **Occurrence and Exposure**
  - Evaluate when a potential change in health or technology exists.
  - 16 State database ~ 13 million analytical results from 41,000 PWSs.
  - Results discussed in the Six-Year FR- based on data from 8,000 to 23,000 PWSs (~34,000 to 200,000 analytical results) per contaminant.
- **Economic Considerations**
  - Consider available economic information when health or technical reason exists for changing an NPDWR. Cannot do a detailed cost analysis at this stage.

Diagram 1 - Protocol Overview and Making the Revise/Not Revise Decisions

Meaning of the Revise/Not Revise Decision
(for the Final Notice - Fall 2002 time frame)

- **"Revise" Decision**
  - EPA plans to initiate rulemaking revision process for particular contaminants.
  - The final decision to revise depends on outcome of analyses performed during the rulemaking process.
- **"Not Revise" Decision**
  - Revision not appropriate at this time, because
    - risk assessment in process;
    - NPDWR remains appropriate after review of available data/information;
    - little/no gain in public health protection and/or significant opportunity for cost savings; or
    - data gaps or research needs.
  - Opportunity to reconsider as part of next review cycle (2002 -2008); however, may accelerate schedule if appropriate.

Preliminary Revise/Not Revise Decisions for 69 NPDWRs



Revise (1) - TCR

No Revise (68)

- Assessment in process/planned (36)
- NPDWR remains appropriate (17)
- Little/No Public Health Gain (12)
- Data Gaps (3)

See the following slides or the Six-Year Review Fact Sheet for a detailed list of how contaminants categorized.

No Revision
Agency Risk Assessments in Process (36)

Acrylamide (TT) (2004 / 2005)
Alachlor (2002 / 2003)
Antimony (2002 / 2003)
Asbestos (2004 / 2005)
Atrazine (2002)
Benzo[a]pyrene (2002 / 2003)
Cadmium (2002 / 2003)
Carbofuran (2002 / 2003)
Carbon tetrachloride (2002 / 2003)
Copper (TT) (2002 / 2003)
* Cyanide (2004 / 2005)
2,4-D (2003 / 2004)
1,2-Dichlorobenzene (2002 / 2003)
1,4-Dichlorobenzene (2002 / 2003)
1,2-Dichloroethane (2002 / 2003)
1,1-Dichloroethylene (2002 / 2003)
* Di(2-ethylhexyl)adipate (2003 / 2004)
Di(2-ethylhexyl)phthalate (2002 / 2003)
Diquat (2002)
Endothall (2003 / 2004)
Ethylbenzene (2002 / 2003)
Ethylene dibromide (2002 / 2003)
Glyphosate (2002 / 2003)
Lindane (2003 / 2004)
Methoxychlor (2002 / 2003)
Pentachlorophenol (2002 / 2003)
PCBs (2002 / 2003)
Simazine (2003 / 2004)
Styrene (2002 / 2003)
2,3,7,8-TCDD (Dioxin) (2002 / 2003)
Tetrachloroethylene (2002 / 2003)
* Thallium (2004 / 2005)
Toluene (2002 / 2003)
1,1,1-Trichloroethane (2003 / 2004)
Trichloroethylene (2002 / 2003)
Xylenes (2002 / 2003)

* Initiated risk assessment as a result of the Six-Year Review

No Revision
Agency Risk Assessments in Process
Key Points

- Many chemicals were undergoing an update to their Agency risk assessment when Six-Year project began
- Policy decision not to duplicate the efforts/resources of the Agency's existing consensus process or perform a fragmented revision
- Several EPA offices involved in updating risk assessments - ORD (18), OPP (11), OW (4), OPPT (1), OSW (1), and Region 8 (1)
- 70 to 80 percent due in 2002-2003 timeframe; rest due after 2003. If compelling reason exists - will revisit the decision before the next review cycle (i.e., off-cycle)
- New health effects information identified because of the Six-Year review for cyanide, di(2-ethylhexyl)adipate, and thallium

Health Effects Review

What information was identified for Cyanide, DEHA and Thallium that necessitated updates to the risk assessments?

- **Cyanide**
  - Present basis for RfD - NOAEL of 10.8 mg/kg/day for thyroid and nervous system effects in a two year study in rats.
  - Data Identified - NOAEL of 4.5 mg/kg/day for reproductive effects in male rats from a 13-week study (ATSDR, 1997).
- **DEHA**
  - Present RfD - NOAEL of 170 mg/kg/day from a developmental study.
  - Data Identified - Same dose in the same study characterized as a LOAEL by WHO (1996).
- **Thallium**
  - Present RfD -NOAEL of 0.2 mg/kg/day (highest dose tested) from a 90-day study in rats.
  - Data Identified - LOAEL for developmental effects (impaired learning ability) of 0.08 mg/kg/day in rats (ATSDR, 1992); NOAEL of 0.2 mg/kg/day used to establish the RfD considered to be a LOAEL by Cal-EPA.

No Revision
NPDWR Remains Appropriate (17)

Barium (EPA 1998)
Dalapon (lit search)
cis-1,2-Dichloroethylene (ATSDR 1996, lit search)
trans-1,2-Dichloroethylene (ATSDR 1996, lit search)
Dinoseb (lit search)
Endrin (ATSDR 1996, lit search)
Epichlorohydrin (TT, zero MCLG)
Hexachlorocyclopentadiene (EPA 2001)
Lead (TT) (ATSDR 1999, zero MCLG)
Mercury (EPA 1997)
Monochlorobenzene (lit search)
Nitrate (1995 NAS, lit search)
Nitrite (1995 NAS, lit search)
Selenium (NAS 2000)
2,4,5-TP (Silvex) (lit search)
1,2,4-Trichlorobenzene (lit search)
Vinyl chloride (EPA 2000, zero MCLG)

No Revision
NPDWR Remains Appropriate - Key Points

- After review of appropriate key elements - no information identified that provides a health or technical basis to change current requirements
- How Did EPA make this determination?
  - Review of the MCLG
  - Review of the MCL or Treatment Technique Requirements
  - Review of "Other Regulatory Provisions"

No Revision
NPDWR Remains Appropriate – No Basis for MCLG Revision

- **6 of these 17 have 1997 or later health risk assessments reflecting negligible or no change in assessment (Ba, HCCP, Pb, Hg, Se and VC).**
- **11 have no risk assessment 1997 or later.**
  - Epichlorohydrin is a carcinogen. No evidence that it has a non-linear mode of action. The zero MCLG remains appropriate.
  - EPA conducted a full toxicological literature search for the remaining 10 contaminants. The search did not identify any studies that warrant revising the health risk assessment or the MCLG.

No Revision
NPDWR Remains Appropriate – No Basis for Revising MCL/TT

- **14 have MCL set at MCLG so MCL remains appropriate.**
- **Vinyl chloride has MCL set based on analytical measurement feasibility. EPA's review indicates practical quantitation level (PQL) remains appropriate at this time.**
- **Lead and epichlorohydrin are treatment technique (TT) rules. EPA's review indicates there is no basis for revising the TT requirements at this time.**
  - Review identified areas for possible research in conjunction with lead; research will be prioritized in context of other drinking water research needs

No Basis for Other Regulatory Revisions
(applies to all No Revision categories)

- **Compliance monitoring and reporting issues.**
  - Most issues raised in context of Chemical Monitoring Reform. Current requirements not changed.
  - New system/new source monitoring addressed as part of radionuclides and arsenic regulation.
  - Flexibility in issuing waivers and assessing vulnerability for certain contaminants; States with primacy have flexibility; source water assessment can be used; vulnerability assessment also being evaluated through another vehicle.
- **Lead and Copper issues addressed in 2000 rulemaking**
- **CCR and PN requirements addressed through CCR and PN rules (outside scope of Six-Year Review).**
- **NTNCWS monitoring - being addressed through another mechanism.**

No Revision
Negligible Gain (12)

Benzene (EPA 2000, zero MCLG)
* *Beryllium* (EPA 1998)
Chlordane (EPA 1998, zero MCLG)
1,2-Dibromo-3-chloropropane (ATSDR 1992, zero MCLG)
1,2-Dichloropropane (zero MCLG, lit search)
Heptachlor (ATSDR 1993, zero MCLG)
Heptachlor epoxide (ATSDR 1993, zero MCLG)
Hexachlorobenzene (ATSDR 1996, zero MCLG)
* *Oxamyl* (EPA 2000)
* *Picloram* (EPA 1998)
Toxaphene (ATSDR 1996, zero MCLG)
1,1,2-Trichloroethane (lit search)

* Contaminants that have a health basis for potential change. Contaminants without an asterisk are based on a technical reason.

No Revision
Negligible Gain - Key Points

- **After review of appropriate key elements**
  - Potential changes to the MCLG and/or MCL identified
  - However, occurrence and exposure indicates negligible gain in public health protection or cost savings while maintaining public health protection
- **How did EPA make this determination?**
  - Integration of health and/or technical information with occurrence and exposure data

No Revision
Technical Basis for Change but Negligible Gain

- **Nine of twelve had potential MCL changes because of analytical feasibility**
  - Health effects - no potential MCLG changes identified
  - MCL originally limited by analytical feasibility (PQL) - Analytical methods review indicates a potentially lower PQL
  - No treatment limitations and no other regulatory revisions identified
  - Occurrence/Exposure review -
    - Evaluated incremental difference between current MCL & the potentially lower PQL to determine additional % PWSs impacted & population exposed
    - Data indicate little/negligible gain in public health protection

No Revision
Occurrence and Exposure Results

Contaminant	Current MCL	Potential MCL	% Systems Impacted*	% Pop Affected*
Benzene	0.005	0.0004	0.33%	0.30%
Chlordane	0.002	0.001	0.00%	0.00%
1,2 DBCP	0.0002	0.0001	0.53%	0.62%
1,2-DCP	0.005	0.0004	0.05%	0.11%
Heptachlor	0.0004	0.0001	0.00%	0.00%
Heptachlor Epoxide	0.0002	0.0001	0.00%	0.00%
HCB	0.001	0.0001	0.003%	0.018%
Toxaphene	0.003	**0.001	0.00%	0.00%
1,1,2-trichloroethane	0.005	***0.003	0.00%	0.00%

* Percent difference between current MCL and potential MCL
** Used 1/3 MCL for Tox *** MCLG for 1,1,2-trichloroethane
Any value less than 0.001% reported as 0.00%

No Revision
Health Basis for Change but Negligible Gain

- **Three of twelve -** potential MCLG changes
  - Health Effects Review
    - Beryllium (Current MCLG/MCL = 0.004 mg/L)
      - 1998 Agency assessment - decrease in RfD
      - Potential increase/decrease in MCLG - depends on 10 x risk mgmt factor (0.01-0.001 mg/L)
    - Oxamyl (Current MCLG/MCL = 0.2 mg/L)
      - 2000 Agency assessment - decrease in RfD
      - Potential decrease in MCLG (0.007 mg/L)
    - Picloram (Current MCLG/MCL = 0.5 mg/L)
      - 1998 Agency assessment - increase in RfD
      - Potential increase in the MCLG (1 mg/L)

No Revision
Health Basis for Change but Negligible Gain
(continued)

- **Three of twelve (continued)**
  - Analytical Methods and Treatment Feasibility
    - No analytical limitations for beryllium or picloram
    - Oxamyl would be limited by PQL (0.02 - 0.04 mg/L)
    - No treatment limitations for beryllium, oxamyl or picloram
  - No other regulatory revisions identified
  - Occurrence/exposure review -
    - Little/negligible gain in public health protection if decrease an MCLG/MCL
    - Negligible cost savings (while maintaining public health protection) for PWSs and their customers if increase an MCLG/MCL.

No Revision
Occurrence and Exposure Results
Beryllium, Oxamyl and Picloram

Contaminant	Current MCL	Potential MCL	% Systems Impacted*	%Pop Affected*
Beryllium	0.004	0.001 0.01	0.99% 0.07%	0.68% 0.02%
Oxamyl	0.2	0.04 0.02 0.007	0.00% 0.00% 0.00%	0.00% 0.00% 0.00%
Picloram	0.5	1	0.00%	0.00%

* Percent difference between current MCL and potential MCL
Any value less than 0.001% reported as 0.00%

No Revision
Data Gaps (3) - Key Points

Chromium (EPA 1998; NTP underway)
Dichloromethane (ATSDR 2000)
Fluoride (NAS 1997; lit search)

- **After review of appropriate key elements**
  - New health or technical information that may affect MCLG and/or MCL
  - However, data gaps exist that need to be resolved
  - Plan to address in next review cycle if data gaps resolved
  - If resolved sooner and compelling reason will consider performing review off-cycle

No Revision
Dichloromethane
Technical Basis for Change but Data Gaps

- **Dichloromethane is analytical feasibility issue**
  - Zero MCLG remains appropriate; MCL limited originally by PQL
  - Analytical methods review - indicates potentially lower PQL
  - Occurrence/Exposure review - indicates potential opportunity for gain in public health protection.
  - Data are insufficient to actually recalculate a specific PQL value using the methodology typically used by EPA.
  - Public comment on whether to gather better data to recalculate the PQL

Contaminant	Current MCL	Potential MCL	% Systems Impacted*	% Pop Affected*
Dichloromethane	0.005	0.00025	4.95%	9.28%

* Percent difference between current MCL and potential MCL

No Revision
Chromium and Fluoride
Health Effects Information but Data Gaps

- **Chromium**
  - 1998 Agency assessment - decrease in RfD
  - Concern in California about Cr +6 and cancer
  - To date no studies to support carcinogenicity by oral ingestion
  - Studies underway by National Toxicology Program (3-5 years before results)
- **Fluoride**
  - Current MCLG/MCL based on skeletal fluorosis
  - Requested that National Academy of Science review new studies published since 1993
  - Also requested NAS to evaluate relative source contribution

Overview

- Current TCR Requirements
- Activities to Date
- Rationale for Revising TCR
- Upcoming Activities

Current TCR Requirements

- **What is the Monitoring Frequency?**
  - Between 1-480 monthly samples, depends on system size & type
  - State may reduce to quarterly in CWSs
  - State may reduce to annually in NCWSs
- **What Must the System do in Response to TC+?**
  - Collect a set of repeat samples for each TC+
  - *E. coli* / fecal coliform testing
  - Five routine samples next month

Current TCR Requirements

(continued)

- **What Constitutes Compliance?**
  - No more than 5.0% of samples TC+/mo if system collects 40+ samples
  - No more than one TC+ if system collects fewer than 40 samples/mo
  - No fecal coliform or *E. coli* positives in repeat samples
  - No TC+ following fecal coliform or *E. coli* positive routine sample
- **What Must the System do in Response to a Violation?**
  - Notify State by end of next business day
  - Notify public per Public Notification Rule

Current TCR Requirements

(continued)

- **What Other Requirements Exist?**
  - Site sampling plan representative of water throughout the distribution system
  - Sanitary surveys every five years
    - NCWSs using protected and disinfected ground water every ten years

Activities to Date
Compilation of Comments Received Since Promulgation

- **Routine monitoring comments**
  - Increase minimum to greater than one sample per year
  - Base sampling frequency on risk (cross connections, SWAP)
  - Waive TC monitoring if undisinfected, no distribution system
  - Increase requirements if MCL or monitoring violation
- **Follow-up monitoring comments**
  - Drop fecal coliforms, keep *E. coli*
  - Drop five routine samples following month
  - Clarify repeats in systems w/o distribution system
  - Better ways exist to determine plumbing problem

Activities to Date
Compilation of Comments Received Since Promulgation *(continued)*

- **MCL comments**
  - Drop MCL for TC, keep for *E. coli*
  - Change to action level
- **Site sampling plan comments**
  - Greater flexibility - emphasize monitoring critical/vulnerable sites
  - Allow for dedicated sampling taps

Activities to Date
M/DBP FACA Agreement in Principle (Sept. 2000)

- Finished water storage and distribution systems may pose public health risks
- WQ problems can be related to infrastructure problems; Aging distribution systems may increase infrastructure problem risks
- As part of TCR 6-year review process EPA should:
  - Evaluate available data and research on aspects of distribution systems that may create risks to public health
  - Work with stakeholders to initiate a process for addressing cross connection control and backflow prevention requirements
  - Consider additional distribution system requirements related to significant health risks

Activities to Date
Distribution System White Papers Drafted

- **Present current information and research on potential health risks posed by:**
  - Biofilms
  - Cross-connections and backflow
  - Intrusion
  - Aging infrastructure/corrosion
  - Covered storage
  - Permeation and leaching
  - Nitrification
  - Contamination following repair/replacement
  - Decay in WQ over time

Activities to Date

Preparation of Notice of Intent

- **EPA intends to undertake a rulemaking process to initiate possible revisions to the TCR**
  - Opportunities exist for reducing implementation burden while assuring public health protection
  - May be appropriate to include this rulemaking in a wider effort to review and address broader issues associated with drinking water distribution systems

Upcoming Activities

- **EPA Intends to Undertake a Rulemaking Process to Initiate Possible Revisions to the TCR**
  - Assess effectiveness of current TCR in reducing public health risk
  - Assess alternate/additional monitoring strategies for reducing the economic burden while maintaining or improving public health protection
- **Complete White Paper Development**
  - Target date - June 2002
  - Will post on OGWDW website
- **Public Stakeholder Meetings**

Schedule for the Six-Year Review

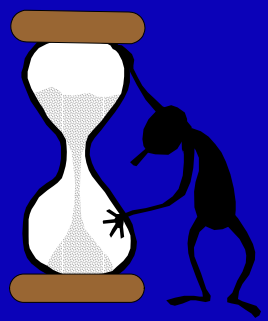
Aug 1999 | Feb-00 | Aug 2000 | Feb-01 | Aug 2001 | Feb-02 | Fall 2002

Review Process

November 1999
Stakeholder Mtg

Protocol Development
and NDWAC Workgroup

August 1999 - Began Six Year Project



April 2002 - June 2002

* Publish Notice - Preliminary Revise/Not Revise Decisions
* 60 day public comment
* Stakeholder Meeting
* Consultation with SAB

~ Fall 2002

* Notice with Final Decisions

Schedule and Next Steps

1) **Published *FR* notice with preliminary decisions - April 17, 2002**

2) **60-Day Comment Period (ends June 17, 2002)**
   1)Stakeholder meeting (held May 30, 2002)

3) ***FR* Notice with Final decisions - Fall 2002 timeframe**